510(k) Summary of Safety and Effectiveness:

EXTREMITY MEDICAL IP Fusion System

APR 1 1 2013

Submitter:	EXTREMITY MEDICAL 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Brian Smekal Director, Regulatory Affairs Phone: (973) 588-8988 Email: bsmekal@extremitymedical.com
Date Prepared	March 26, 2013
Trade Name	EXTREMITY MEDICAL IP Fusion System
Classification Name and Number	Smooth or threaded metallic bone fixation fastener 21 CFR 888.3040
Product Code	HWC
Predicate Devices	1. Kirschner Wires K073674 2. Osteomed Hand Fusion System K111419 3. EXTREMITY MEDICAL Screw System, Extremity Medical K121417
Device Description	The Extremity Medical IP Fusion System is designed to allow arthrodesis of the interphalangeal joints of the hand. The system has two intra-operative configurations: a cannulated or non-cannulated lag screw, and an intramedullary Post for engaging the lag screw. The Post consists of a threaded cylinder with an eyelet through the head at to accommodate the lag screw. The axis of the eyelet and the lag screw couple at an oblique angle, which forms a reference angle for the intended fusion. The system includes common instrumentation for application of surgical bone screws within the human body, such as drills, guide wires, countersinks, reamers, drill and guide wire guides, and a screwdriver.
Indications for use	The Extremity Medical IP Fusion System is intended for reduction and internal fixation of arthrodesis of the interphalangeal joints of the hand.
Statement of Technological Comparison	The EXTREMITY MEDICAL IP Fusion System and its predicate devices have the same indications for use; have a similar design; are made of similar materials, and have equivalent mechanical properties.
Non-clinical Testing	Bench testing, including pull-out strength, torque, and static and dynamic bending was performed and compared to the predicate devices. Clinical

	simulations in cadavers were performed to verify the surgical technique.
Clinical Testing	No clinical testing was performed.
Conclusion	The EXTREMITY MEDICAL IP Fusion System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, materials, design, test data and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Extremity Medical, LLC.
% Mr. Brian Smekal
Director, Regulatory Affairs
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

Letter dated: April 11, 2013

Re: K130120
Trade/Device Name: EXTREMITY MEDICAL IP Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 28, 2013
Received: January 30, 2013

Dear Mr. Smekal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130120

Device Name: EXTREMITY MEDICAL IP Fusion System

Indications for Use:

The Extremity Medical IP Fusion System is intended for reduction and internal fixation of arthrodesis of the interphalangeal joints of the hand.

Prescription Use X **AND/OR** **Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices